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EXAMINER

GLASS, CHRISTOPHER W

ART UNIT PAPER NUMBER

2878

DATE MAILED: 05/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,764

Applicant(s)

FOLESTAD ET AL.

Examiner

Christopher W. Glass

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 November 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

1. The drawings are objected to because in Figure 2, box 106, “detector” is misspelled. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities:

On lines 23-24 of page 1, it appears that “powders several mm:s why information” has words missing or contains other minor errors.

On line 31 of page 7, “incecent” should read “incident”.

On line 16 of page 8, “analyse” should be replaced by “analysis”, and on line 20 of this page, “etc” should read “etc.”.

On line 9 of page 10, it appears that “with he spectrometer 32” should be changed to “with the spectrometer 32”.

Appropriate correction is required.

Claim Objections

3. Claims 24 and 31 are objected to because of the following informalities: the preamble of claim 24 recites “in one of claims 1-10”, and the preamble of claim 31 recites “any of claims 26-30”; the language of these portions could be changed to read “in any one of claims...”, as used in the preambles of claims 23 and 32, for instance. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,813,988 to Alfano et al. (hereafter Alfano).

Regarding claim 25: Alfano shows in Figures 1(a – c) a means for use in analysis of a turbid sample which comprises directing an excitation radiation beam (from INPUT LIGHT) onto the sample (ABSORBING OBJECT in SCATTERING MEDIUM) and measuring (through the use of OPTICAL FIBER BUNDLE TO STREAK CAMERA) the intensity of emitted radiation from the thus radiated sample as a function of both wavelength of the emitted radiation and photon propagation time through the sample (see also Column 3, lines 37-67 and Column 7, line 66 – Column 8, line 25).

6. Claim 25 is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,400,396 to Bowker et al. (hereafter Bowker).

Bowker discloses (e.g. in Figure 2) a means for use in an analysis of a turbid sample comprising means **22** for directing an excitation radiation beam **12** onto the sample (not shown in Figure 2) and means (comprising streak tube **34**, detector array **48**, and lens **36**) for measuring the intensity of emitted radiation from the thus radiated sample as a function of both wavelength of the emitted radiation and photon propagation time through the sample (see also summary of the invention in Column 2).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-8,11,14-24,26-28,31-38, and 40-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano, in view of U.S. Patent No. 5,828,452 to Gillespie et al. (hereafter Gillespie). Apparatus and method claims will be grouped according to functional similarity, since the apparatus is considered capable of performing the method claimed.

Regarding claims 1-4,15 and 19 (as dependent from one of claims 1-8),26,32,33,41(as dependent from one of claims 1-8), and 44: Alfano shows in Figure 1(a) a means for use in analysis of a turbid sample, comprising a means (INPUT LIGHT) for providing an excitation beam of radiation and irradiating a turbid sample (ABSORBING OBJECT, in SCATTERING MEDIUM) with the excitation beam of radiation, and a means (OPTICAL FIBER BUNDLE TO

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STREAK CAMERA) for detecting the intensity of emitted radiation from the sample as a function of both the wavelength of the emitted radiation and the photon propagation time through the sample. The emitted radiation comprises transmitted radiation from the sample and diffusely reflected radiation from the sample (see also configurations of Figures 1(b) and 1(c)). The sample is shown positioned in a scattering medium within a cube-shaped container, and the INPUT LIGHT excitation beams are focused through the connected optical fibers. While Alfano does not expressly teach this means as being used to analyze a solid pharmaceutical sample in the form of a tablet, capsule, bulk powder, or pharmaceutical dose, or a dispersion, Gillespie teaches that it is well known in the art to perform turbid analysis on any of a plurality of types of samples in a wide range of applications, such as “medical diagnostics, clinical chemistry, environmental analysis, and other fields” (see discussion of Column 1, lines 54-65). It would have been obvious, therefore, to one having ordinary skill in the art at the time the invention was made to use the analysis means of Alfano with any of these types of samples, and further since this only involves matters of intended use. It has been held that a recitation with respect to the manner in which a claimed invention is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Regarding claims 5-7: In the means of Alfano, the excitation beam is a pulsed excitation beam presenting a pulse train of excitation pulses, the step of detecting the intensity as a function of photon propagation time is performed in time synchronism with the excitation pulses, and the excitation pulses have a pulse length shorter than the photon propagation time, selected short enough in relation to the photon propagation time such that any undesired interference between

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the intensity measurements relating to two subsequent excitation pulses is prevented (see Column 3, lines 49-59 and Column 7, line 66 – Column 8, line 25).

Regarding claims 8 and 40: The excitation beam of Alfano is not specifically disclosed as being an intensity modulated excitation beam from an intensity modulated lamp, and However, it is well known in the art to use modulated light sources in such analysis means. Gillespie teaches that “a xenon arc lamp is a popular choice for the excitation light source” in conventional systems (Column 2, lines 21-22). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modulate the intensity of the light source in Alfano, in order to provide optimal excitation conditions for analyzing the sample.

Regarding claims 11 (as dependent from one of claims 1-8), 27, and 28: the detection of the intensity of emitted radiation from the sample as a function of time is performed with the use of a time-resolved detection unit in the form of a streak camera (see Column 3, lines 60-67 and Column 8, lines 2-25).

Regarding claims 14 (as dependent from one of claims 1-8) and 31: Bowker does not expressly teach a spatial-resolved detection of intensity. However, this is well known in the art, as taught by Gillespie, and it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ spatially-resolved detection means in the intensity detection, in order to “spatially resolve the emitted light as a function of wavelength” (Column 3, lines 20-21).

Regarding claims 16-18: the means of Alfano shown in Figures 1(a-c) has means for irradiating a first surface and a second surface of the sample, as shown by the configurations of Figures 1(b) and 1(c), which comprise light sources and detectors provided on multiple walls and

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in orthogonal relative arrangement. The first surface and the second surface, corresponding to operation of separate light sources on different walls, as shown, are irradiated at different points in time (see for instance the setup discussed in Column 10, lines 32-33).

Regarding claims 20 (as dependent from one of claims 1-8), 21,22,34-36,43, and 45: Alfano discloses using an excitation beam comprising radiation having a frequency in the range corresponding to wavelengths from 700nm to 1500nm (see Column 10, lines 20-23).

Regarding claims 23 (as dependent from one of claims 1-8) and 37: Alfano discloses using an excitation beam comprising visible light (see Column 8, lines 2-4).

Regarding claims 24 (as dependent from one of claims 1-8) and 38: Alfano does not specifically teach the excitation beam as comprising UV radiation. However, it is well known to use excitation radiation in this range. Gillespie teaches that "In some applications it may be preferable to use a laser as the excitation source...If the source is pulsed, as are most ultraviolet lasers, time-resolved emission spectra can be collected" (Column 2, lines 25-33). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use UV radiation in the means of Alfano, since this range is well-known as being advantageous in certain applications of such analysis configurations.

Regarding claim 42: Alfano does not specifically show irradiating oppositely directed surfaces of the sample. However, the Figure 1(c) arrangement has two light sources arranged in an orthogonal relationship to irradiate different surfaces, and it would have been obvious to one having ordinary skill in the art at the time the invention was made to arrange the radiation sources and detection means of Alfano to irradiate oppositely directed surfaces, in order to analyze these sides of the sample, and since this would only involve rearranging the parts already

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shown in this embodiment. It has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

9. Claims 1,2,5-7,11,13-16,20-22,24,26-28,30-36,38,39,41, and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bowker, in view of Gillespie. Apparatus and method claims will be grouped according to functional similarity, since the apparatus is considered capable of performing the method claimed.

Regarding claims 1,15 (as dependent from one of claims 1,3, and 5-10),19 (as dependent from one of claims 1,3, and 5-10),26,32,33,41 (as dependent from one of claims 1,3, and 5-10), and 44: Bowker discloses in Figure 2 a means for use in quantitative analysis of a turbid sample, having a laser means **22** for providing a focused excitation beam of radiation, which irradiates the turbid sample (not shown in this figure) with the excitation beam. Also disclosed is a means (comprising streak tube **34**, detector array **48**, and lens **36**) for detecting the intensity of emitted radiation from the sample as a function of both the wavelength of the emitted radiation and the photon propagation time through the sample. Bowker does not expressly show a means for positioning the turbid sample. However, it would have been obvious to one having ordinary skill in the art to position the sample in a secure, stationary means such as a container on an inspection stage or other positionable means, in order to facilitate accurate analysis. Further, while Bowker does not expressly teach this means as being used to analyze a solid pharmaceutical sample in the form of a tablet, capsule, bulk powder, or pharmaceutical dose, or a dispersion, Gillespie teaches that it is well known in the art to perform turbid analysis on any of a plurality of types of samples in a wide range of applications, such as “medical diagnostics, clinical chemistry, environmental analysis, and other fields” (see discussion of Column 1, lines

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54-65). It would have been obvious, therefore, to one having ordinary skill in the art at the time the invention was made to use the analysis means of Bowker with any of these types of samples, and further since this only involves matters of intended use. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d (1987).

Regarding claim 2: The emitted radiation from the sample comprises diffusely reflected radiation 30 from the sample.

Regarding claims 5-7: The excitation beam 12 is a pulsed excitation beam presenting a pulse train of excitation pulses, and the step of detecting the intensity as a function of the photon propagation time is performed in time synchronism with the excitation pulses; the excitation pulses have a pulse length shorter than the photon propagation time, and wherein the length is selected short enough in relation to the photon propagation time such that any undesired interference between intensity measurements relating to two subsequent excitation pulses is prevented (see Column 2, lines 2-39 and Column 4, lines 48-61).

Regarding claims 11 (as dependent from one of claims 1,3, and 5-10),13 (as dependent from one of claims 1,3, or 5-10),27,28, and 30: The detection of the intensity of emitted radiation from the sample as a function of time is performed with the use of a time resolved detection unit 34 and time-gated system (see Column 2, lines 8-39 and also background discussion of Column 1, lines 30-42).

Regarding claims 14 (as dependent from one of claims 1,3, and 5-10) and 31: Bowker does not expressly teach a spatial-resolved detection of intensity. However, this is well known in

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the art, as taught by Gillespie, and it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ spatially-resolved detection means in the intensity detection, in order to “spatially resolve the emitted light as a function of wavelength” (Column 3, lines 20-21).

Regarding claim 16: The step of irradiating the sample with the excitation beam **12** comprises the step of irradiating a first surface of the solid sample (see Column 2, lines 7-8 and Column 4, lines 48-50).

Regarding claims 20 (as dependent from one of claims 1,3, and 5-10), 21,22,34-36,43, and 45: The excitation beam of Bowker comprises radiation “in the infrared, 1.06 micrometers” (1060 nm; Column 7, lines 1-2).

Regarding claims 24 (as dependent from one of claims 1,3, and 5-10) and 38: Bowker does not specifically teach the excitation beam as comprising UV radiation. However, it is well known to use excitation radiation in this range. Gillespie teaches that “In some applications it may be preferable to use a laser as the excitation source...If the source is pulsed, as are most ultraviolet lasers, time-resolved emission spectra can be collected” (Column 2, lines 25-33). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use UV radiation in the means of Bowker, since this range is well-known as being advantageous in certain applications of such analysis configurations.

Regarding claim 39: In Bowker, the means for generating the excitation beam comprises one or more diode lasers (see Figure 5 and discussion of the laser and projection optics in Column 6, line 54 - Column 7, line 4).

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10. Claims 9,10,12 (as dependent from one of claims 1-8), and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano, in view of Gillespie and U.S. Patent No. 5,936,739 to Cameron et al. (hereafter Cameron). Alfano does not expressly disclose using phase comparison in the detection, and does not specifically teach using a phase-resolved detection unit. However, Gillespie discusses conventional photoluminescence systems, in which “During phase-resolved measurements with an amplitude modulated source the lifetime is determined from the demodulation factor or the phase-shift factor” (Column 8, lines 10-13), and Cameron teaches that phase-resolved approaches can be advantageous since they allow “the detection of the majority of the re-emitted light (diffuse) in the form of photon density waves over large penetration depths” (Column 2, lines 28-31). It would have been obvious to one having ordinary skill in the art to modify the means of Alfano to employ phase comparison and phase-resolved detection, in order to offer these advantages.

11. Claims 9,10,12 (as dependent from one of claims 1,3, and 5-10), and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bowker, in view of Gillespie and Cameron. Bowker does not expressly disclose using phase comparison in the detection, and does not specifically teach using a phase-resolved detection unit. However, Gillespie discusses conventional photoluminescence systems, in which “During phase-resolved measurements with an amplitude modulated source the lifetime is determined from the demodulation factor or the phase-shift factor” (Column 8, lines 10-13), and Cameron teaches that phase-resolved approaches can be advantageous since they allow “the detection of the majority of the re-emitted light (diffuse) in the form of photon density waves over large penetration depths” (Column 2, lines 28-31). It would have been obvious to one having ordinary skill in the art to modify the

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means of Bowker to employ phase comparison and phase-resolved detection, in order to offer these advantages.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Patent No. 6,124,937 to Mittenzwey et al. discloses a method and device for combined absorption and reflectance spectroscopy, and teaches the use of ultraviolet excitation radiation and a CCD type detector.

U.S. Patent No. 5,422,719 to Goldstein concerns a multi-wavelength spectrofluorometer which is capable of employing any of several different wavelengths of excitation radiation, and teaches measuring turbid samples.

U.S. Patent No. 5,758,653 to Schotland discloses a simultaneous absorption and diffusion imaging system and method using direct reconstruction of scattered radiation.

U.S. Patent No. 5,303,026 to Strobl et al. concerns an apparatus and method for spectroscopic analysis of scattering media, using a wavelength-tunable, pulsed source, and which can measure intensity of emitted radiation from a sample as a function of excitation light wavelength.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher W. Glass whose telephone number is 703-305-1980.


The examiner can normally be reached 9:30am-6:00pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Porta can be reached at 703-308-4852. The fax phone number for the organization where this application or proceeding is assigned is 703-308-7722.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0956.

cg
May 4, 2003


STEPHONE ALLEN
PRIMARY EXAMINER